

NATIONAL INSTITUTE FOR OCCUPATIONAL SAFETY AND HEALTH  
(NIOSH)

CENTERS FOR DISEASE CONTROL AND PREVENTION  
U.S. DEPARTMENT OF HEALTH AND HUMAN SERVICES

**CONSENT TO PARTICIPATE IN A HEALTH HAZARD EVALUATION**

**HETA-2006-0354**

1. You are being asked to participate in a NIOSH medical survey to assess lung function in current workers at the Bennington State Office Building. The Vermont Department of Health (VDH) requested technical assistance from the NIOSH Division of Respiratory Disease Studies for this assessment as part of the VDH investigation of lung disease occurrence in several State Office Building workers. The purpose of this medical survey is to identify other workers who might have lung disease and to determine the possible reasons why they were affected.
2. The survey will include the following procedures:
  - A. **Baseline Spirometry.** You will be asked to breathe in as deeply as you can through a tube that you place in your mouth and then forcefully blow out as quickly and completely as possible. You will be asked to do this at least three times, and possibly several more times. This test may be tiring, and you may feel momentary lightheadedness or chest discomfort. If, at any time, you feel unable to continue, the test will be stopped. This is a standard medical test that measures how much air you can exhale from your lungs and how fast you can exhale it. This test typically takes 10 minutes.
  - B. **Methacholine Challenge Test.** Following spirometry, you may be asked to inhale a mist of methacholine and then to repeat spirometry. This test may show that your lungs are sensitive to contaminants in the air. Methacholine challenge is used as a clinical test to diagnose asthma. You may experience a brief episode of coughing or chest tightness, which is reversed with a bronchodilator. Less frequently, you may experience headache, flushing, or sweating, which should last less than an hour. This test takes approximately 40 minutes, but may take longer depending on your reaction to the methacholine.

**C. Bronchodilator Administration.** If you are unable to perform the methacholine challenge test, you may be asked to breathe in a bronchodilator medication from an inhaler or puffer. The bronchodilator is a type of medication commonly used to open air passages in your lungs. After several minutes, you will be asked to repeat the breathing tests. This will determine the improvement in lung function. You may feel lightheaded or jittery for about 30 minutes as a result of inhaling the bronchodilator. This medication might temporarily increase your pulse rate. You will be checked to see if that happens. This test takes about 30 minutes.

**D. Carbon Monoxide Diffusing Capacity.** You will breathe in a harmless gas from a mouthpiece, then hold your breath for 10 seconds and then breathe out. This will be repeated no more than 5 times. You may feel some lightheadedness that will go away within a few minutes. This is a standard medical test that tells how well your lungs transfer oxygen. This test should take about 30 minutes.

All together, your participation should take no longer than an hour and a half and for most workers should take only one hour.

3. The benefits to you from participating in the study include the free medical tests described above. Your participation may also benefit your co-workers, and possibly other people, as a result of what is learned from this study. NIOSH will provide you and your doctor (if you wish) with all findings from your medical tests. We will do this in approximately three weeks.

One disadvantage, besides the slight discomfort and inconvenience described above, is that a test result may be outside the range of "normal" even though nothing is wrong. This could result in a recommendation for further medical evaluation that would not have been needed otherwise. Negative test results do not necessarily rule out illness because some workers will be using medications at therapeutic doses during the testing.

4. Most of the procedures described above are standard medical tests; there are no alternative procedures.
5. Injury from this project is unlikely. But if injury did result, medical care would not be provided by NIOSH, other than first aid. If you are injured through negligence of a NIOSH employee, you may be able to obtain compensation under Federal Law. If you want to file a claim against the Federal government your contact point is: Public Health Service Claims Office: (301) 443-1904. If you are injured through the negligence of a NIOSH contractor, your claim would be against the contractor, not the Federal government. If an injury should occur to you as the result of your participation, you should contact Dr. Richard Kanwal, Project Officer, at (304) 285-5932 or Dr. Mike Colligan, (513) 533-8222, the chair of the NIOSH Human Subjects Review Board.
6. The National Institute for Occupational Safety and Health (NIOSH) of the Centers for Disease Control and Prevention (CDC), an agency of the Department of Health and Human Services, is authorized to collect this information, including your social security number, under provisions of the Public Health Service Act, Section 301 (42 U.S.C. 241); Occupational Safety and Health Act, Section 20 (29 U.S.C. 669); and Federal Mine Safety and Health Act of 1977, Section 501 (30 U.S.C. 95). The information you supply is voluntary and there is no penalty for not providing it. The data will be used to evaluate illnesses resulting from occupationally-related exposures, to determine their causes and to prevent them in the future. Data will become part of CDC Privacy Act system 09-20-0147, "Occupational Health Epidemiological Studies" and may be disclosed: to appropriate State or local health departments to report certain communicable diseases; to private contractors assisting NIOSH; to other collaborating researchers under certain limited circumstances to conduct further investigations; to one or more potential sources of vital statistics to make a determination of death; to the Department of Justice in the event of litigation; and to a congressional office assisting individuals in obtaining their records. An accounting of the disclosures that have been made by NIOSH will be made available to you upon request. Except for these and other permissible disclosures expressly authorized by the Privacy Act or in limited circumstances when required by the Freedom of Information Act, no other disclosure may be made without

your written consent.

By signing this consent form you are agreeing that NIOSH may share all of your medical test results, including your personal identifying information, with the Vermont Department of Health.

7. If you have any reaction to the tests or procedures, you should contact Dr. Richard Kanwal at 800-232-2114 or directly at (304) 285-5932. You should also contact Dr. Kanwal if you have any questions concerning this study or your participation.
8. Your participation is voluntary and you may withdraw your consent and your participation in this study at any time without penalty or loss of benefits to which you are otherwise entitled.

## 9. SIGNATURES

I have read this consent form and I agree to participate in this study.

PARTICIPANT \_\_\_\_\_  
Age \_\_\_\_\_ Date \_\_\_\_\_  
(signature)

I, the NIOSH representative, have accurately described this study to the participant.

REPRESENTATIVE \_\_\_\_\_  
Date \_\_\_\_\_  
(signature)